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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/768,571

01/29/2004

Karla Weaver

10123/00701

6350

7590 03/11/2008  
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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

03/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/768,571	<b>Applicant(s)</b> WEAVER ET AL.	
	<b>Examiner</b> THEODORE J. STIGELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14 and 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/22/2008</u> .                                               | 6) <input type="checkbox"/> Other: _____                          |

**.DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10, 12-14, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Frisch *et al.* (4,447,237). Frisch *et al.* discloses a valve housing (511), a flexible membrane (84) and a slit (83). (See Figure 7 and 8) Frisch *et al.* discloses coating all blood contacting surfaces with a suitable anticoagulant material such as TDMAC-heparin. (See Column 12 Lines 15-30) The flexible membrane is disclosed to comprise silicone. (See Claim 2) As to claim 10 and 12-13, Frisch discloses an elongated body (41), a lumen (not referenced), a valve (511), and an anticoagulant coating comprising heparin (not referenced). (See Figure 6-8) The valve comprises a flexible membrane, such as silicone, and a slit (83). As to claim 14 and 16-17, Frisch *et al.* disclose a lumen (not referenced), a housing (511), a valve (513), a slit (83) and an anticoagulant coating comprising heparin (not referenced). (See Figure 6-8) The valve is taught to be under a sufficient amount of pressure to seal against a pressure of at least 300 mm Hg from the blood. (See Claim 11)

Claims 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Steigerwald (5,009,391). Steigerwald disclose a valve comprising a valve housing (22),

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a plurality of flexible members (90, 94) with at least one slit (92a-c, 96a-c) and a fluid directing recess (24). (See Figure 5 and 6)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch *et al.* (4,447,237) in view of Steigerwald (5,009,391). Frisch *et al.* discloses a valve housing (511), a flexible membrane (84) and a slit (83). (See Figure 7 and 8) Frisch *et al.* discloses coating all blood contacting surfaces with a suitable anticoagulant material such as TDMAC-heparin. (See Column 12 Lines 15-30) The flexible membrane is disclosed to comprise silicone. (See Claim 2) Frisch *et al.* fails to disclose abutting flexible membranes. Steigerwald teaches abutting two flexible membranes adjacent to one another. (See Fig. 4d.) Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Frisch *et*

*al.* with the teachings of Steigerwald to provide a valve with abutting flexible membranes.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steigerwald (5,009,391) in view of Frisch *et al.* (4,447,237). Steigerwald disclose a valve comprising a valve housing (22), a plurality of flexible members (90, 94) with at least one slit (92a-c, 96a-c) and a fluid directing recess (24). (See Figure 5 and 6) Steigerwald fails to disclose a nonthrombogenic coating on the fluid contacting surfaces. Frisch *et al.* teaches coating all blood contacting surfaces with a suitable anticoagulant material such as TDMAC-heparin. (See Column 12 Lines 15-30)

Claims 1-10, 12-14, and 16-21 are rejected under 35 U.S.C. 103(a) as being obvious over Weaver *et al.* (US 2004/0267185) in view of Frisch *et al.* (4,447,237).

Weaver discloses a pressure activated valve comprising a valve housing (18, 20), a flexible membrane (100) disposed in the valve housing, the membrane including a slit (112) extending through the housing so that the membrane may be moved between an open and closed configuration based on fluid pressure delivered by a dialysis machine.

Weaver does not teach to include a nonthrombogenic coating on the contacting surfaces of the membrane.

Frisch *et al.* discloses a valve housing (511), a flexible membrane (84) and a slit (83). (See Figure 7 and 8) Frisch *et al.* discloses coating all blood contacting surfaces with a suitable anticoagulant material such as TDMAC-heparin. (See Column 12 Lines 15-30) The flexible membrane is disclosed to comprise silicone. (See Claim 2)

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Weaver with the teachings of Frisch et al. to provide a valve with a nonthrombogenic coating to prevent blood clotting.

Claims 1-10, 12-14, and 16-21 are rejected under 35 U.S.C. 103(a) as being obvious over Moorehead et al. (US 2005/0049555) in view of Frisch et al. (4,447,237).

Moorehead discloses a pressure activated valve comprising a valve housing (15), a flexible membrane (24) disposed in the valve housing, the membrane including a slit (26) extending through the housing so that the membrane may be moved between an open and closed configuration based on fluid pressure delivered by a dialysis machine.

Moorehead does not teach to include a nonthrombogenic coating on the contacting surfaces of the membrane.

Frisch et al. discloses a valve housing (511), a flexible membrane (84) and a slit (83). (See Figure 7 and 8) Frisch *et al.* discloses coating all blood contacting surfaces with a suitable anticoagulant material such as TDMAC-heparin. (See Column 12 Lines 15-30) The flexible membrane is disclosed to comprise silicone. (See Claim 2)

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Moorehead with the teachings of Frisch et al. to provide a valve with a nonthrombogenic coating to prevent blood clotting.

The applied references have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome

by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

### ***Response to Arguments***

Applicant's arguments filed 2/19/2008 have been fully considered but they are not persuasive. The new limitations added to the independent claims are being interpreted as functional limitations. The examiner notes that a dialysis machine is not being claimed. It is the examiner's position that if the cited references were hooked up to a dialysis machine, the machine could deliver, or at least be adapted to deliver, a fluid pressure strong enough to at least partially open the valve. Even if limitations could be read into the claim from the specification, the applicant has not given any specific ranges of pressures to be used to open the valves. In conclusion, the examiner is interpreting the new limitations as functional limitations which do not convey any structural limitation that would separate the claimed invention from the prior art.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Theodore J. Stigell

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763